Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 34-35, 38-39, 41-42, 44, 46, 52, and 55-57 are pending in the application, with claims 1, 34, and 52 being the independent claims. Claims 2-33, 36-37, 40, 43, 45, 47-51, and 53-54 were previously sought to be canceled without prejudice to or disclaimer of the subject matter therein. Claims 58-66 are herewith sought to be canceled without prejudice to or disclaimer of the subject matter therein. Applicants reserve the right to pursue any of the canceled subject matter in related applications. Claims 1, 34, and 52 are sought to be amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Rejections of Claims 58-66 under 35 U.S.C. § 112, First Paragraph and 35 U.S.C. § 103(a)

The Examiner rejected claims 58-66 under 35 U.S.C. § 112, First Paragraph (New Matter and Enablement) and 35 U.S.C. § 103(a). While not agreeing with the Examiner's assertions or bases for rejection, Applicants have canceled claims 58-66 purely to further prosecution, rendering the rejections moot. Applicants reserve the right to pursue any of the canceled subject matter in related applications.

II. Claim Rejections under 35 U.S.C. § 112, First Paragraph, New Matter

Claims 1, 34-35, 38-39, 41-42, 44, 46, 52, and 55-56 were rejected under 35 U.S.C. § 112, First Paragraph, as allegedly including new matter based on the language "a promoter which functions in hepatocytes." Office Action at pages 4-6. The Examiner recommended at page 6 of the Office Action "that Applicant simply remove the limitation of the promoter functional in hepatocytes and simply require that the gene in the vector is expressed in the hepatocyte, subsequent to transformation of the hepatocyte."

While not agreeing with the Examiner's assertions regarding new matter, Applicants have amended the claims purely in the interests of furthering prosecution and based on the Examiner's recommendation to remove the language "a promoter which functions in hepatocytes," noting that the method claims already require expression of the therapeutic gene products in hepatocytes subsequent to transformation.

Based on the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the new matter rejection.

III. Claim Rejections under 35 U.S.C. § 102 Based on Wilson et al.

Claims 52 and 55 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. 6,001,557 (hereinafter, 'Wilson *et al.*'). Applicants respectfully traverse the Examiner's rejection as it applies to the pending claims for reasons of record and as further clarified and expanded upon herewith.

The Examiner alleges that Wilson *et al.* anticipates Applicants' claims by teaching the viral particles of Claim 52. Claim 52 requires that **both** the first and second

viral vectors of the pharmaceutical composition "are ***provided*** in viral particles;" the first viral particle contains a therapeutic gene product, the second viral particle does not. Applicants noted previously that the shuttle vector and helper virus taught by Wilson *et al.* are not both in the form of viral particles when administered to a cell. As alleged support for maintaining the rejection, the Examiner states that: "the particles are made **after** infection of the cells with both viruses . . .". *See* Office Action at page 9, emphasis added. However, even if the *cell* of Wilson *et al.* contains viral particles ***after*** infection, the latter is a **method** of producing a viral particle in a cell from a "composition" of shuttle vector and helper virus administered to the cell, where ***the "composition" never contains two viral particles***. In contrast to the requirements of Claim 52:

(1) Wilson *et al.* teaches a first "composition" with **only** a helper virus that is used to infect a cell, and a second "composition" with **only** a shuttle vector plasmid that is used to transfect a cell *after* administration of the first "composition." *See* Wilson *et al.* at col. 13, lines 45-49, stating that "helper virus is used to infect cells . . which are then **subsequently transfected** with an pAdΔ shuttle vector containing a selected transgene . . .". In this instance, neither "composition" contains two viral particles. Moreover, the shuttle vector plasmid in the second composition is not packaged (*i.e.*, in the form of a viral particle) prior to transfection. *Id.*; and

(2) Wilson *et al.* teaches a "composition" of a plasmid **conjugated** by poly-L-lysine to a helper virus. *See* Wilson *et al.* at col. 13, line 65 to col. 14, line 5. While the helper virus is a viral particle, the shuttle vector plasmid is **not** in the form of a viral particle when conjugated to the helper virus *prior* to infection of the

cell. *Id.* As such, ***only*** **one** component of the conjugate is a viral particle, ***not*** **two** non-conjugated viral particles as recited in the composition of Claim 52.

Given the above, none of the "compositions" taught by Wilson *et al.* contain **two** viral particles as recited in Claim 52. The shuttle vector is never in the form of a viral particle when administered with the helper virus. In contrast to the shuttle vector plasmid of Wilson *et al.*, the viral vector comprising the therapeutic gene product in the composition of Claim 52 is always a viral particle and does not require any function of a helper virus to be packaged.

As the latter makes clear, Wilson *et al.* does not teach administration of a pharmaceutical composition containing two separate viral particles wherein one viral particle reduces Kupffer cell function. Given that a proper rejection under 35 U.S.C. § 102 requires anticipation of **each and every** element of a claim, the anticipation rejection can not stand given the failures of Wilson *et al.* to teach each and every element of Applicants' Claim 52. *See* M.P.E.P. § 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987), and *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909, 107 S. Ct. 2490 (1987).

Based on the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the novelty rejection.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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